GENERAL PROCEDURAL POLICIES

CITIZEN PETITIONS OR SUITABILITY PETITIONS: POLICY AND PROCEDURES

Background:

An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. In addition, the request for a formal advisory opinion under 21 CFR 10.85 is processed as a citizen petition. The submission of citizen petitions is governed by §10.30. Petitions are submitted to the Dockets Management Branch (HFA-305) (DMB) where they are reviewed for compliance with §10.30. If the petition is acceptable for filing, DMB files, acknowledges, and assigns a docket number to the petition. If the petition is not adequate for filing, DMB returns it to the petitioner. Suitability petitions as defined by the Generic Animal Drug and Patent Term Restoration Act are a special type of citizen petition. The Act became law on November 16, 1988 (Public Law 100-670).

1. Processing Citizen Petitions (excluding Suitability Petitions):

   DMB forwards filed petitions to the appropriate Center or office for preparation of a response. Under 21 CFR 10.30(e)(2), a written response to the petition is required within 180 days of filing. The response may consist of:

   a. Concurrence with the petition which may result in appropriate administrative action such as publication of a FEDERAL REGISTER document;

   b. Denial of the petition, which generally will include a discussion of the basis for denial;

   c. A tentative response, indicating why the agency is unable to reach a decision on the petition. The tentative response may also indicate the ultimate agency response, and may specify when a final response may be furnished.

   Final responses to citizen petitions are ordinarily the responsibility of Associate Commissioner for Regulatory Affairs. Petition responses will be prepared for his signature. When the citizen petition is closely related to a proposed or final rule, the final response will be prepared for the signature of the Deputy Commissioner for Policy.

A petitioner whose petition has been denied, may request administrative reconsideration under §10.33. A request for reconsideration is normally required to be submitted within 30 days of the denial.

The agency administrative record for the Citizen Petition is maintained by the Dockets Management Branch, showing: (1) The docket number (assigned by DMB); (2) The date the petition was filed by the DMB; (3) The name of the petitioner; (4) The subject matter involved; and (5) The disposition of the petition.

The Policy and Regulations Team, HFV-6, is the contact point within the Center for receipt of the petition; coordination among offices, if necessary; consolidating the necessary reviews and actions; logging the movements of the petition and response package; circulating the response package for proper signatures and monitoring timeliness of response.

When received by HFV-6, the petition is logged into the Citizen Petition file indicating Docket Number, the 180-day due date, and other identifying information, including the name and mail code of the CVM unit(s) where it is assigned for consulting review and preparation of correspondence.

The preparation of the response to a Citizen Petition may be assigned to any unit within the Center depending upon the expertise involved. The expertise and resources required for response are determined by the Team Leader of the Policy and Regulations Team, in conjunction with the appropriate Office Directors.

A final response to a citizen petition will be prepared for the signature of the Associate Commissioner for Regulatory Affairs unless the petition is closely related to a proposed or final rule. In the latter case, it will be prepared for the signature of the Deputy Commissioner for Policy. The preparation of the response may be assigned to any unit within the Center depending upon the expertise involved. Under §5.31(e)(2), the Center Director may sign an interim response. The response should be accompanied by an action memorandum describing the nature of the petition and the rationale for the response with a recommendation that the letter be signed and issued. The docket number should be in the upper-right-hand corner of the first page. The distribution copy of the letter to be filed by Dockets Management Branch should not include concurrence and distribution information. At completion, HFV-6 determines that DMB has received copies of all correspondence and memoranda relating to the docket (except internal working papers or memoranda (including action memorandum) that are protected from disclosure under the

Freedom of Information Act).

Ordinarily a draft response will be prepared with the assistance of the CVM liaison attorney in the Office of Chief Counsel (OCC). The response package should be circulated for signature of the Division Director, Office Director and Center Director. If the issue impacts on more than one division, it should be concurred in by each. Following final sign-off by the Center, responses for the signature of the Associate Commissioner for Regulatory Affairs are forwarded to the Division of Compliance Policy (HFC-230) who in turn will log it into their system, and forward it on to the Office of Chief Counsel. The package is then forwarded for OCC's final concurrence. It is then forwarded to the Associate Commissioner for Regulatory Affairs (HFC-1) for signature, issuance of response, and distribution of copies, including those to DMB. If the petition response involves a FEDERAL REGISTER publication, Regulations and Policy Management Staff (HF-26) will also be included in the review and the Deputy Commissioner for Policy (HF-22) for signature.

Responses to petitions related to a proposed or final rule, and prepared for the signature of the Deputy Commissioner for Policy, will be forwarded to the Regulations Policy and Management Staff (RPMS) (HF-26) following final sign-off by the Center. RPMS will obtain final OCC concurrence, signature, issue the response, and distribute copies.

2. Processing Suitability Petitions:

Suitability petitions are defined in the Generic Animal Drug and Patent Term Restoration Act (FFDCA, section 512(n)(3)), and are processed in CVM as a special type of citizen petition. If a sponsor wants to submit an abbreviated application for a new animal drug whose active ingredients (in fixed-combination drug products), route of administration, dosage form, or strength differ from that of an approved new animal drug, or whose use with other animal drugs in animal feed differs from that of an approved new animal drug, the sponsor may submit a Suitability Petition seeking permission to file such an application.

The Dockets Management Branch (HFA-305) forwards the filed petition to the Quality Assurance Support Team, HFV-102, Office of New Animal Drug Evaluation, for preparation of a written response.

The Center, by statute, shall approve or disapprove a Suitability Petition within 90 days of the date the petition is submitted (filed).

The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM, are authorized to issue responses to citizen petitions submitted under §10.30, seeking a determination of the suitability of an abbreviated new animal drug application for an animal drug product. Refer to §5.31(f)(7) for authority delegation.

The response to a Suitability Petition may consist of: (1) Approval of the petition; (2) Denial of the petition, which generally will include a discussion of the reasons for the denial; or (3) A tentative response, indicating why the agency is unable to reach a decision on the petition.

Ordinarily a draft response will be prepared by HFV-102 and will incorporate the recommendations of the CVM Generic Animal Drug Committee. The response package is circulated for signatures to the appropriate Division Director(s); to the CVM liaison attorney in the Office of Chief Counsel; to the Chief, Quality Assurance Support Team; and to the Director, Office of New Animal Drug Evaluation. Following issuance of the letter, a copy of the final response relating to the docket is forwarded to the Dockets Management Branch to become part of the public file. The distribution copy of the letter to be filed by the Dockets Management Branch should not include concurrence and distribution information.

The Administrative Record for the Suitability Petition is maintained by the Dockets Management Branch, showing: (1) The docket number; (2) The date the petition was filed by the Dockets Management Branch; (3) The name of the petitioner; (4) The subject matter involved; and (5) The disposition of the petition.

A petitioner whose petition has been denied may request administrative reconsideration of the denial following the procedures set forth in §10.33. Such a request must be based solely on the information and views contained in the original petition and must be submitted in accordance with §10.20 in the format outlined in §10.33. A request for reconsideration is required to be submitted within 30 days after the date of the denial of the Suitability Petition, and is also filed with the Dockets Management Branch.

If there is additional information, not included as part of the original petition, that the petitioner would like the agency to consider, a new Suitability Petition should be submitted under §10.30 including all the necessary information.

3. References:

21 CFR 5.31; §10.30; §10.33; §10.85; Generic Animal Drug and Patent Term

Restoration Act; Federal Food, Drug, and Cosmetic Act, section 512(n).